

LUPEROX® 575**1. PRODUCT AND COMPANY IDENTIFICATION****Company**

Arkema Inc.
900 First Avenue
King of Prussia, Pennsylvania 19406

Functional Additives

Customer Service Telephone Number: (800) 331-7654
(Monday through Friday, 8:00 AM to 5:00 PM EST)

Emergency Information

Transportation: CHEMTREC: (800) 424-9300
(24 hrs., 7 days a week)
Medical: Rocky Mountain Poison Center: (866) 767-5089
(24 hrs., 7 days a week)

Product Information

Product name: LUPEROX® 575
Synonyms: Peroxyester
Molecular formula: C₁₃H₂₆O₃
Chemical family: Organic peroxide - peroxyesters
Molecular weight: 230.34 g/mol
Product use: initiator/catalyst

2. HAZARDS IDENTIFICATION**Emergency Overview**

Color: Clear - colourless
Physical state: liquid
Odor: sweet

***Classification of the substance or mixture:**

Organic peroxides, Type D, H242
Skin sensitisation, Category 1, H317
Reproductive toxicity, Category 2, H361
Acute aquatic toxicity, Category 1, H400
Chronic aquatic toxicity, Category 1, H410

*For the full text of the H-Statements mentioned in this Section, see Section 16.

LUPEROX® 575**GHS-Labeling**

Hazard pictograms:



Signal word:

Danger**Hazard statements:**

H242 : Heating may cause a fire.
H317 : May cause an allergic skin reaction.
H361 : Suspected of damaging fertility or the unborn child.
H410 : Very toxic to aquatic life with long lasting effects.

Supplemental Hazard Statements:

Organic peroxide.
Hazardous decomposition may occur.
Temperature controlled.
Thermally unstable - refrigeration required.

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Precautionary statements:

Prevention:

P201 : Obtain special instructions before use.
P202 : Do not handle until all safety precautions have been read and understood.
P210 : Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P220 : Keep/Store away from clothing/ combustible materials.
P234 : Keep only in original container.
P261 : Avoid breathing gas/mist/vapours/spray.
P272 : Contaminated work clothing should not be allowed out of the workplace.
P273 : Avoid release to the environment.
P280 : Wear protective gloves/ eye protection/ face protection.
P281 : Use personal protective equipment as required.

Response:

P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.
P308 + P313 : IF exposed or concerned: Get medical advice/ attention.
P333 + P313 : If skin irritation or rash occurs: Get medical advice/ attention.
P363 : Wash contaminated clothing before reuse.
P391 : Collect spillage.

Storage:

P405 : Store locked up.
P410 : Protect from sunlight.
P411 + P235 : Maximum storage temperature is specified on label and in section 7 of SDS. Keep cool.
P420 : Store away from other materials.

Disposal:

P501 : Dispose of contents/ container to an approved waste disposal plant.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Hexaneperoxoic acid, 2-ethyl-, 1,1-dimethylpropyl ester	686-31-7	>= 96 %	H242, H317, H400, H410
2-Butanol, 2-methyl-	75-85-4	< 4 %	H225, H312, H332, H319, H335

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Potassium octoate	Proprietary*	0.146 %	H315, H318, H361
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*The specific chemical identity is withheld because it is trade secret information of Arkema Inc.

**For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES
4.1. Description of necessary first-aid measures:
Inhalation:

If inhaled, remove victim to fresh air.

Skin:

In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eyes:

Immediately flush eye(s) with plenty of water.

Ingestion:

If swallowed, DO NOT induce vomiting. Get medical attention. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms/effects, acute and delayed:

For most important symptoms and effects (acute and delayed), see Section 2 (Hazard Statements and Supplemental Information) and Section 11 (Toxicology Information) of this SDS.

4.3. Indication of immediate medical attention and special treatment needed, if necessary:

Unless otherwise noted in Notes to Physician, no specific treatment noted; treat symptomatically.

5. FIREFIGHTING MEASURES
Extinguishing media (suitable):

Water spray, Carbon dioxide (CO₂), Foam, Dry chemical

Protective equipment:

Fire fighters and others who may be exposed to products of combustion should wear full fire fighting turn out gear (full Bunker Gear) and self-contained breathing apparatus (pressure demand / NIOSH approved or equivalent).

Further firefighting advice:

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Fight fire with large amounts of water from a safe distance.
Cool closed containers exposed to fire with water spray.
Closed containers of this material may explode when subjected to heat from surrounding fire.
After a fire, wait until the material has cooled to room temperature before initiating clean-up activities.
Do not allow run-off from fire fighting to enter drains or water courses.
Fire fighting equipment should be thoroughly decontaminated after use.

Fire and explosion hazards:

Contact with incompatible materials or exposure to temperatures exceeding the SADT may result in a self accelerating decomposition reaction with release of flammable vapors which may autoignite.
When burned, the following hazardous products of combustion can occur:
Carbon oxides
Sulphur oxides
Hazardous organic compounds

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, Emergency procedures, Methods and materials for containment/clean-up:**

Prevent further leakage or spillage if you can do so without risk. Evacuate area of all unnecessary personnel. Ventilate the area. Eliminate all ignition sources. Avoid generation of vapors. Contain and collect spillage with non-combustible absorbent material such as sodium bicarbonate, sodium carbonate, calcium carbonate, clean sand or non-acidic clay and then wet down (dampen) the mixture with water. DO NOT USE peat moss. Sweep or scoop up using non-sparking tools and place into suitable properly labeled containers for prompt disposal. The sweepings should be wetted down further with water. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits.

Protective equipment:

Appropriate personal protective equipment is set forth in Section 8.

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7. HANDLING AND STORAGE

Handling**General information on handling:**

Temperature controlled! Cool and maintain proper temperature for product.
Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.
Avoid breathing vapor or mist.
Do not taste or swallow.
Do not get in eyes, on skin, or on clothing.
Keep away from heat, sparks and flames.
No smoking.
Use only with adequate ventilation.
Wash thoroughly after handling.
Prevent product contamination.
Keep container tightly closed and away from combustible materials.
Keep only in the original container.
Container hazardous when empty.
Do not reuse container as it may retain hazardous product residue.
Improper disposal or reuse of this container may be dangerous and/or illegal.

Storage**General information on storage conditions:**

Keep refrigerated. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Outside or detached storage is preferred. Store in well ventilated area away from heat and sources of ignition such as flame, sparks and static electricity. Store out of direct sunlight in a cool well-ventilated place. Store in original container. Store away from combustibles and materials to avoid. Refer also to National Fire Protection Association (NFPA) Code 400, Hazardous Materials Code.

Storage stability – Remarks:

Keep refrigerated. Follow the recommended storage temperatures provided in this Section in order to maintain stability and oxygen content.

Storage incompatibility – General:

Store away from excessive heat, sources of ignition, and reactive materials.

Store separate from:

Strong acids

Strong bases

Strong oxidizing agents

Reducing agents

Amines

Accelerators

Friedel - Crafts reaction catalyst

transition metal salts

metal ions

Brass

Copper

Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

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Temperature tolerance – Do not store above:
41 °F (5 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Engineering controls:

Investigate engineering techniques to reduce exposures below airborne exposure limits or to otherwise reduce exposures. Provide ventilation if necessary to minimize exposures or to control exposure levels to below airborne exposure limits (if applicable see above). If practical, use local mechanical exhaust ventilation at sources of air contamination such as open process equipment.

Consult ACGIH ventilation manual or NFPA Standard 91 for design of exhaust systems.

Respiratory protection:

Avoid breathing vapor or mist. Where airborne exposure is likely or airborne exposure limits are exceeded (if applicable, see above), use NIOSH approved respiratory protection equipment appropriate to the material and/or its components. Full facepiece equipment is recommended and, if used, replaces need for face shield and/or chemical goggles. Consult respirator manufacturer to determine appropriate type equipment for a given application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure or where exposure limit may be significantly exceeded, use an approved full face positive-pressure, self-contained breathing apparatus or positive-pressure airline with auxiliary self-contained air supply. Respiratory protection programs must comply with 29 CFR § 1910.134.

Skin protection:

Wear appropriate chemical resistant protective clothing and chemical resistant gloves to prevent skin contact. Consult glove manufacturer to determine appropriate type glove material for given application. Wear chemical goggles, a face shield, and chemical resistant clothing such as a rubber apron when splashing may occur. Rinse immediately if skin is contaminated. Remove contaminated clothing immediately and wash before reuse. Clean protective equipment before reuse. Provide a safety shower at any location where skin contact can occur. Wash thoroughly after handling.

Eye protection:

Where eye contact may be likely, wear chemical goggles and have eye flushing equipment available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color:	Clear - colourless
Physical state:	liquid
Odor:	sweet
Odor threshold:	No data available
Flash point	The flashpoint of this product is greater than the Self Acceleration Decomposition Temperature (SADT).

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Auto-ignition temperature:	No data available.
Lower flammable limit (LFL):	No data available
Upper flammable limit (UFL):	No data available
pH:	No data available
Density:	0.9 g/cm ³ (50 °F (10 °C))
Specific Gravity (Relative density):	No data available
Vapor pressure:	6.6 mmHg (60.1 °F (15.6 °C))
Vapor density:	No data available
Boiling point/boiling range:	Decomposes before boiling. Rate of decomposition increases with rising temperature.
Melting point/range:	< -112 °F (< -80 °C)
Freezing point:	No data available
Evaporation rate:	No data available
Solubility in water:	insoluble
Viscosity, dynamic:	No data available
% Volatiles:	100 %
Molecular weight:	230.34 g/mol
Oil/water partition coefficient:	No data available.
Self-Accelerating Decomposition Temperature (SADT):	104 °F (40 °C) (Method: Heat Accumulation Storage Test)
Thermal decomposition:	No data available
Active oxygen content:	> 6.67 %
Flammability:	See GHS Classification in Section 2

10. STABILITY AND REACTIVITY

LUPEROX® 575**Stability:**

This material is chemically unstable and should only be handled under specified conditions. See HANDLING AND STORAGE section of this SDS for specified conditions.

Hazardous reactions:

Hazardous polymerization does not occur.

Materials to avoid:

Strong acids
Strong bases
Strong oxidizing agents
Reducing agents
Amines
Accelerators
Friedel - Crafts reaction catalyst
transition metal salts
metal ions
Brass
Copper
Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Conditions / hazards to avoid:

See HANDLING AND STORAGE section of this SDS for specified conditions. SADT - Self Accelerating Decomposition Temperature. Lowest temperature at which the tested package size will undergo a self-accelerating decomposition reaction. This reaction will generate flammable vapors which may autoignite. The length of time to generate a decomposition reaction, after the SADT has been reached or exceeded, is dependent upon how much the SADT has been exceeded and the length of time needed for the reaction exotherm (heat spike from increasing decomposition rate) to initiate a rapid decomposition reaction. Typically, SADT is inversely proportional to package size. Larger packages will have a lower SADT due to smaller ratio to heat transfer area to volume of product.

Hazardous decomposition products:

Temperatures at or above SADT can result in the release of hazardous decomposition products which are flammable and may autoignite.

Thermal decomposition giving flammable and toxic products :

Carbon oxides
sulfur oxides
Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

Data on this material and/or its components are summarized below.

Data for LUPEROX® 575**Acute toxicity****Dermal:**

Acute toxicity estimate > 5,000 mg/kg.

Inhalation:

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4 h Acute toxicity estimate > 10 mg/l. (dust/mist)

Data for Hexaneperoxoic acid, 2-ethyl-, 1,1-dimethylpropyl ester (686-31-7)**Acute toxicity****Oral:**

Practically nontoxic. (rat) LD0 > 5.000 mg/kg.

Dermal:

Practically nontoxic. (rat) LD50 > 5.000 mg/kg.

No deaths occurred. (rabbit) LD0 > 2.000 mg/kg.

Inhalation:

Practically nontoxic. (rat) 4 h LC50 = 42.2 mg/l. (t-butyl peroctoate, similar material, aerosol)

Skin Irritation:

Practically non-irritating. (rabbit) Irritation Index: 1,0/8,0.

Eye Irritation:

Not irritating. (rabbit) Irritation Index: 0.0/110.

Skin Sensitization:

May cause an allergic skin reaction. Guinea pig maximization test. (guinea pig) Skin allergy was observed.

Repeated dose toxicity

Repeated oral administration to rat / affected organ(s): liver, kidney / signs: changes in organ weights, hair loss, clinical chemistry changes

Genotoxicity**Assessment in Vitro:**

Both positive and negative responses for genetic changes were observed in laboratory tests using: bacteria

No genetic changes were observed in a laboratory test using: animal cells

Genotoxicity**Assessment in Vivo:**

No genetic changes were observed in a laboratory test using: mice

Data for 2-Butanol, 2-methyl- (75-85-4)**Acute toxicity****Oral:**

Practically nontoxic. (rat) LD50 = 5,184 mg/kg.

Dermal:

Harmful in contact with skin. (rabbit) LD50 = 1,720 mg/kg.

LUPEROX® 575**Inhalation:**

Harmful if inhaled. (rat) 6 h LC50 > 10.8 mg/l. (vapour)

Specific target organ toxicity - single exposure:

May cause respiratory irritation.

Skin Irritation:

Not irritating. (rabbit) (open patch exposure)

Eye Irritation:

Causes serious eye irritation. (rabbit)

Skin Sensitization:

Not a sensitizer. LLNA: Local Lymph Node Assay. (mouse) No skin allergy was observed

Repeated dose toxicity

Repeated inhalation administration to rat and dog / affected organ(s): liver, central nervous system, eye / signs: central nervous system depression, excessive tearing

Repeated inhalation administration to mouse / No adverse systemic effects reported.

Repeated dermal administration to rabbit / No adverse systemic effects reported.

Genotoxicity**Assessment in Vitro:**

No genetic changes were observed in laboratory tests using: bacteria, yeast, animal cells, human cells

Developmental toxicity

Exposure during pregnancy. Inhalation (rat) / No birth defects were observed.

Reproductive effects

Reproductive/Developmental Effects Screening Assay. Inhalation (rat) / No toxicity to reproduction.

Data for Potassium octoate (Proprietary)**Acute toxicity****Oral:**

May be harmful if swallowed. (rat) LC50 = 2,043 mg/kg.

Dermal:

No deaths occurred. (rat) LD0 > 2,000 mg/kg.

Inhalation:

No deaths occurred. (rat) 8 h LC0 > 0.11 mg/l. (vapour)

Skin Irritation:

Causes skin irritation. (rabbit)

Eye Irritation:

Causes serious eye damage. (rabbit) (data for a similar material)

LUPEROX® 575**Skin Sensitization:**

Not a sensitizer. Repeated exposure. (guinea pig) No skin allergy was observed

Repeated dose toxicity

Repeated exposure dietary administration to mouse / affected organ(s): liver / signs: structural organ changes, changes in organ weights / No significant impairment of function.

Repeated exposure dietary administration to rat / affected organ(s): liver / signs: structural organ changes, changes in organ weights / No significant impairment of function.

Genotoxicity**Assessment in Vitro:**

No genetic changes were observed in laboratory tests using: bacteria, animal cells

Genotoxicity**Assessment in Vivo:**

No genetic changes were observed in laboratory tests using: mice

Developmental toxicity

Exposure during pregnancy. Oral (rat) / No birth defects were observed. (levels produced toxic effects in the mothers and offspring, delays in development, skeletal variations, data for a similar material)

Exposure during pregnancy. Oral (rabbit) / No birth defects were observed. (at doses that produce effects in mothers, data for a similar material)

Reproductive/Developmental Effects Screening Assay. drinking water (rat) / No birth defects were observed. (delays in development, data for a similar material)

Reproductive effects

Reproductive/Developmental Effects Screening Assay. drinking water (rat) / Effects on fertility and offspring / (impaired pup growth and development, data for a similar material)

Other information

The information presented is from a representative material with a similar structure. The results vary depending on the size and composition of the test substance.

12. ECOLOGICAL INFORMATION**Chemical Fate and Pathway**

Data on this material and/or its components are summarized below.

Data for Hexaneperoxoic acid, 2-ethyl-, 1,1-dimethylpropyl ester (686-31-7)**Biodegradation:**

Readily biodegradable. (28 d) biodegradation 62 %

Octanol Water Partition Coefficient:

log Pow: = 4.56

Data for 2-Butanol, 2-methyl- (75-85-4)**Biodegradation:**

Not readily biodegradable. (28 d) biodegradation 40 - 50 % / OECD Test Guideline 310

LUPEROX® 575**Octanol Water Partition Coefficient:**

log Pow: = 0.77, = 77 °F (25 °C)

Ecotoxicology

Data on this material and/or its components are summarized below.

Data for Hexaneperoxoic acid, 2-ethyl-, 1,1-dimethylpropyl ester (686-31-7)**Aquatic invertebrates:**Toxic. *Daphnia magna* (Water flea) 48 h EC50 = 3.7 mg/l**Algae:**Very toxic. *Pseudokirchneriella subcapitata* (green algae) 72 h ErC50 = 0.28 mg/l**Microorganisms:**

Respiration inhibition / Activated sludge 3 h EC50 > 1,000 mg/l

Chronic toxicity to aquatic plants:*Pseudokirchneriella subcapitata* (green algae) 72 d EC10 (growth rate) = 0.023 mg/l**Data for 2-Butanol, 2-methyl- (75-85-4)****Aquatic toxicity data:**Practically nontoxic. *Leuciscus idus* (Golden orfe) 48 h LC50 = 2,430 mg/l**Aquatic invertebrates:**Practically nontoxic. *Daphnia magna* (Water flea) 48 h EC50 = 540 mg/l**Algae:**Practically nontoxic. *Scenedesmus subspicatus* 96 h EC50 > 500 mg/l**Microorganisms:**

Respiration inhibition / Activated sludge 30 min EC20 = > 1,000 mg/l

13. DISPOSAL CONSIDERATIONS**Waste disposal:**

Dilution followed by incineration is the preferred method. Dilution ratio of 10:1 in a clean, compatible, combustible solvent (i.e., Fuel Oil #2, mineral oil) will reduce reactivity hazard during incineration and transportation. Dispose of in accordance with federal, state and local regulations. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits. Note: Chemical additions to, processing of, or otherwise altering this material may make this waste management information incomplete, inaccurate, or otherwise inappropriate. Furthermore, state and local waste disposal requirements may be more restrictive or otherwise different from federal laws and regulations.

Take appropriate measures to prevent release to the environment.

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14. TRANSPORT INFORMATION

US Department of Transportation (DOT)

UN Number : 3115
Proper shipping name : Organic peroxide type D, liquid, temperature controlled
Technical name : (tert-Amyl peroxy-2-ethylhexanoate, <=100%)
Class : 5.2
Marine pollutant : yes
Control temperature : 68 °F (20 °C)
Emergency temperature : 77 °F (25 °C)

International Maritime Dangerous Goods Code (IMDG)

UN Number : 3115
Proper shipping name : ORGANIC PEROXIDE TYPE D, LIQUID, TEMPERATURE CONTROLLED
Technical name : (TERT-AMYL PEROXY-2-ETHYLHEXANOATE, <=100%)
Class : 5.2
Marine pollutant : yes
Control temperature : 68 °F (20 °C)
Emergency temperature : 77 °F (25 °C)

15. REGULATORY INFORMATION

Chemical Inventory Status

EU. EINECS	EINECS	Conforms to
United States TSCA Inventory	TSCA	The components of this product are all on the TSCA Inventory.
Canadian Domestic Substances List (DSL)	DSL	All components of this product are on the Canadian DSL
China. Inventory of Existing Chemical Substances in China (IECSC)	IECSC (CN)	Conforms to
Japan. ENCS - Existing and New Chemical Substances Inventory	ENCS (JP)	Conforms to
Japan. ISHL - Inventory of Chemical Substances	ISHL (JP)	Conforms to
Korea. Korean Existing Chemicals Inventory (KECI)	KECI (KR)	Conforms to
Philippines Inventory of Chemicals and Chemical Substances (PICCS)	PICCS (PH)	Conforms to
Australia Inventory of Chemical Substances (AICS)	AICS	Conforms to

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United States – Federal Regulations

SARA Title III – Section 302 Extremely Hazardous Chemicals:

The components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.

SARA Title III - Section 311/312 Hazard Categories:

Acute Health Hazard, Reactivity Hazard, Chronic Health Hazard

SARA Title III – Section 313 Toxic Chemicals:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):

<u>Chemical name</u>	<u>CAS-No.</u>	<u>Reportable quantity</u>
2-Butanol, 2-methyl-	75-85-4	100 lbs

United States – State Regulations

New Jersey Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
2-Butanol, 2-methyl-	75-85-4

New Jersey Right to Know – Special Health Hazard Substance(s)

<u>Chemical name</u>	<u>CAS-No.</u>
2-Butanol, 2-methyl-	75-85-4

Pennsylvania Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
Hexaneperoxoic acid, 2-ethyl-, 1,1-dimethylpropyl ester	686-31-7

2-Butanol, 2-methyl-	75-85-4
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Sulfuric acid disodium salt, decahydrate	7727-73-3
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Pennsylvania Right to Know – Environmentally Hazardous Substance(s)

<u>Chemical name</u>	<u>CAS-No.</u>
Sulfuric acid disodium salt, decahydrate	7727-73-3

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California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive defects.

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

H225	Highly flammable liquid and vapour.
H242	Heating may cause a fire.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H361	Suspected of damaging fertility or the unborn child.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Miscellaneous:

Other information:	Back-up or emergency refrigeration should be available in case primary refrigeration is lost. Emergency dry ice source(s) should be known in case of refrigeration failure. Temperature in storage areas should be monitored. Refrigeration systems should have high temperature alarms to warn of loss of refrigeration.
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Latest Revision(s):

Reference number:	200008340
Date of Revision:	03/28/2017
Date Printed:	03/29/2017

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Arkema has implemented a Medical Policy regarding the use of Arkema products in Medical Devices applications that are in contact with the body or circulating bodily fluids (<http://www.arkema.com/en/social-responsibility/responsible-product-management/medical-device-policy/index.html>) Arkema has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by Arkema for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, Arkema strictly prohibits the use of any Arkema products in Medical Device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. The Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation,

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permanent or temporary implantable devices , and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices.

It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade Arkema products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements (FDA or other national drug agencies) It is the sole responsibility of the manufacturer of the medical device to conduct all necessary tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance obligations. Any decision regarding the appropriateness of a particular Arkema material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.

